IN THE U.S. DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

REBECCA WOJTOWICZ,	Case No: 7:13-04693-CS
and))
ERIC WOJTOWICZ, Plaintiffs,)) FIRST AMENDED COMPLAINT
Fiamuns,)
v.	Pamela A. Borgess (0072789) James G. O'Brien (0088460)
BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER PHARMA AG; and BAYER OY; Defendants.	 ZOLL, KRANZ & BORGESS, LLC 6620 W. Central Ave., Suite 100 Toledo, OH 43617 Tel. (419) 841-9623 Fax: (419) 841-9719 Email: pamela@toledolaw.com Email: jim@toledolaw.com
	Counsel for Plaintiffs

Now come Plaintiffs Rebecca and Eric Wojtowicz, wife and husband, by and through the undersigned counsel, and, pursuant to Case Management Orders 13 and 14, bring this First Amended Complaint against Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG, and Bayer Oy.

NATURE OF THE ACTION

1. This is an action brought by Plaintiffs Rebecca and Eric Wojtowicz for damages suffered as a direct and proximate result of Plaintiff Rebecca Wojtowicz's use of the defective and unreasonably dangerous pharmaceutical product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured,

designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by the Defendants.

2. As a result of her use of Mirena®, Plaintiff Rebecca Wojtowicz suffered injuries to her person including, but not limited to, perforation of her uterus, migration outside the uterus, and the surgical removal of the Mirena® product in August 2010.

THE PARTIES

- 3. At all times relevant hereto, Plaintiffs Rebecca and Eric Wojtowicz, resided at 3629 Oakview Drive, Girard, Trumbull County, Ohio 44420.
- 4. Plaintiff Eric Wojtowicz is the husband of Rebecca Wojtowicz.
- 5. Defendant Bayer Healthcare Pharmaceuticals, Inc. is and at all times relevant, was a corporation organized and existing under the laws of the State of Delaware, having a principle place of business at 67 Whippany Road, Whippany, NJ 07981. On information and belief, Defendant is a citizen of Delaware and New Jersey.
- 6. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.
- 7. Berlex Laboratories Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.
- 8. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for the contraceptive device Mirena®.
- 9. At all times relevant, Defendant Bayer Healthcare Pharmaceuticals, Inc. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or

indirectly through third parties, subsidiaries or related entities, the intrauterine contraceptive device Mirena®.

- 10. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, its predecessors, successors and assigns and its officers, directors, employees, agents, representatives, and any and all other persons acting on its behalf.
- 11. Upon information and belief, Defendant Bayer Pharma AG is a company domiciled in Germany and is the parent/holding company of Defendant Bayer Healthcare Pharmaceuticals, Inc.
- 12. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG has transacted and conducted business in the State of Ohio and derived substantial revenue from interstate commerce.
- 13. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG expected or should have expected that its acts would have consequences within the United States of America, and the State of Ohio in particular and derived substantial revenue from interstate commerce.
- 14. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG exercises dominion and control over Defendant Bayer Healthcare Pharmaceuticals, Inc.
- 15. Upon information and belief, at all relevant times, Defendant Bayer Pharma AG exercises dominion and control over Defendant Bayer Healthcare Pharmaceuticals, Inc.
- 16. Upon information and belief, Defendant Bayer Oy is organized and exists under the laws of Finland and is headquartered at Pansiontie 47 20210 Turku, Finland.

- 17. Upon information and belief, Defendant Bayer Oy is the current owner of the trademark relating to Mirena®.
- 18. In the interest of clarity, this Complaint refers to Defendant Bayer Healthcare Pharmaceuticals, Inc., Defendant Bayer AG, and Defendant Bayer Oy collectively as Bayer, Defendant, or Defendants.
- 19. Defendants do business in Ohio, where Plaintiff was implanted with the intrauterine contraceptive device Mirena®, through the sales of Mirena® and other prescription drugs in the state.
- 20. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device Mirena®.
- 21. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.
- 22. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

JURISDICTION AND VENUE

- 23. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.
- 24. Venue is proper in the Northern District of Ohio, Eastern Division pursuant to 28 U.S.C.A. § 1391, as a substantial part of the events giving rise to these claims occurred within this district, including the prescription and use of Mirena®, as well as Plaintiff's resulting injuries.
- 25. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitutions and pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Mirena® within this District.
- 26. Defendants expected or should have expected that their business activities could or would have consequences within the State of Ohio, as well as throughout the United States.

TAG-ALONG ACTION

27. This is a potential tag-along action and in accordance with 28 U.S.C. § 1407 and has been transferred to the United States District Court for the Southern District of New York for inclusion in *In re Mirena IUD Products Liability Litigation*, MDL 2434 (Hon. Cathy Seibel).

FACTS Mirena® Background

- 28. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:
- 29. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases $20 \mu g/day$ of levonorgestrel, a prescription medication used as a contraceptive.
- 30. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.
- 31. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendants admit "[i]t is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.
- 32. The Mirena® intrauterine system ("IUS") is placed within seven (7) days of the first day of menstruation and remains in the uterus for up to five (5) years. If continued use is desired after five years, the old system must be discarded and a new one inserted.
- 33. Mirena®'s label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.
- 34. Mirena®'s label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

- 35. Defendants have a history of overstating the efficacy of Mirena® while understating the potential safety concerns.
- 36. In or around December 2009, Defendants were contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.
- 37. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena's package insert states that at least 5% of clinical trial patients reported a decreased libido after use.
- 38. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.
- 39. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage is a woman becomes pregnant on Mirena®.
- 40. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

- 41. Upon information and belief, Defendants knew or should have known about the risks of multiple, serious adverse events associated with Mirena® use and still promoted, sold, advertised, and marketed the use of Mirena®.
- 42. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Mirena® had been tested and was found to be safe and/or effective for its indicated use.
- 43. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Mirena® for use as a contraceptive, all of which evinced a callous, reckless, willful, deprayed indifference to the health, safety and welfare of Plaintiff.
- 44. Defendants knew and were aware or should have been aware that Mirena® had not been sufficiently tested, was defective in its design and testing, and/or lacked adequate and/or sufficient warnings.
- 45. Defendants knew or should have known that Mirena® had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.
- 46. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants also fraudulently concealed and intentionally omitted the following material information:
 - a. That Mirena® is not as safe as other available contraceptives;

- b. That the risks of adverse events with Mirena® was not adequately tested and/or known by Defendants;
- c. Plaintiff was put at risk of experiencing serious and dangerous side effects including, but not limited to, device migration and perforation, as well as other severe and personal injuries, physical pain, and mental anguish; and/or
- d. That Mirena® was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.
- 47. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Mirena®.
- 48. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Mirena®, including Plaintiff.
- 49. Upon information and belief, Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Mirena® with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Mirena® as a contraceptive.
- 50. Upon information and belief, Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Mirena® in their labeling, advertising, product inserts, promotional material or other marketing efforts.
- 51. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representative, employees, distributors, agents and/or detail persons.

- 52. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Mirena®, as set forth herein.
- 53. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Mirena®.
- 54. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of Mirena® in a timely manner, yet they failed to provide such warning.

FACTS REGARDING PLAINTIFF REBECCA WOJTOWICZ

- 55. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:
- 56. Plaintiff Rebecca Wojtowicz was prescribed Mirena® by her health care provider.
- 57. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase Mirena® to her detriment.
- 58. Plaintiff's physician inserted the Mirena in Plaintiff in January of 2010.
- 59. At that time Plaintiff was unaware of the concealed information concerning the safety and efficacy of Mirena®, including, but not limited to, the risk of spontaneous perforation and migration, and had no way to determine the truth behind Defendants' concealment and omissions.

suffered serious and life-threatening injuries resulting from the migration of the Mirena® including, but not limited to, uterine perforation, as well as other severe and personal injuries of a permanent and lasting in nature, including surgical removal of the

As a result of using Defendants' product Mirena®, in June 2010, Plaintiff

Mirena®, physical pain and mental anguish, diminished enjoyment of life, medical,

health, and incidental and related expenses.

60.

61. Plaintiff first learned that Mirena® was defective, could cause spontaneous

uterine perforation and migration outside the uterus, and that Defendants in fact knew,

but had failed to disclose that this was "not [an] unexpected occurrence with Mirena®,"

upon receipt of a letter from Defendants dated April 8, 2011.

62. Plaintiff did not discover, nor did she have any reason to discover that her injury

was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth

herein, until after receiving this April 8, 2011 letter.

CAUSES OF ACTION

COUNTS I-IV

Defective Manufacturing/Construction (O.R.C. § 2307.74)
Defective Design/Formulation (O.R.C. § 2307.75)
Defective Warning/Instruction (O.R.C. § 2307.76)
Defective Due to Nonconformity with Representation (O.R.C. § 2307.77)

- 63. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.
- 64. At all times relevant to this action, Defendants were the manufacturers, as defined at Ohio Revised Code § 2307.71, and distributors, which designed, produced, created, made, constructed and/or assembled the Mirena® that was placed into the stream of commerce.

- 65. The Mirena® expected to and did reach the ultimate users, including Plaintiff, without substantial change in the condition it was sold.
- 66. The Mirena® intrauterine devices manufactured, designed, sold, distributed, supplied, promoted and/or place in the stream of commerce by Defendants were defective in their:
 - a. Manufacture and construction pursuant to the provisions of Ohio Revised Code § 2307.74;
 - b. Design pursuant to the provisions of Ohio Revised Code § 2307.75;
 - c. Inadequate warning or instruction pursuant to the provisions of Ohio Revised Code § 2307.76, and/or
 - d. Failure to conform, when it left the control of Defendants, to their representations, pursuant to the provisions of Ohio Revised Code § 2307.77.
- 67. Defendants' Mirena® was defective in that at the time Mirena® left the control of Defendant, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.
- 68. Mirena® was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.
- 69. At all times herein mentioned, Mirena® was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said Mirena® was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.
- 70. The nature and magnitude of the risk of harm associated with the design and formulation of Mirena®, including uterine migration and perforation, is high in light of

the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

- 71. It is highly unlikely that Mirena® users would be aware of the risks associated with Mirena® through either warnings, general knowledge or otherwise. Plaintiff was not aware of said risks.
- 72. The likelihood was high that the design or formulation would cause the harm of uterine migration and perforation, in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.
- 73. The design or formulation did not conform to any applicable public or private product standard that was in effect when Mirena® left the control of its manufacturer, the Defendants.
- 74. The design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner as a reversible form of contraceptive. It was more dangerous than Plaintiff expected.
- 75. The intended or actual utility of Mirena® is not of such benefit to justify the risk of uterine migration, perforation and even infertility.
- 76. There was both technical and economic feasibility, at the time Mirena® left Defendants' control, of using an alternative design or formulation that would not cause uterine migration or perforation.
- 77. The defective design or formulation of Mirena® was not caused by an inherent characteristic of the Mirena® which is a generic aspect of all contraceptive medications that cannot be eliminated without substantially compromising Mirena®'s usefulness or

desirability and which is recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to prevent contraception, without the harmful side effects that can result from Mirena® use.

- 78. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiff suffered.
- 79. Defendant had a duty to warn Plaintiff of the risks associated with Mirena®, namely, the risk of spontaneous migration and perforation.
- 80. Defendants knew, or in the exercise or reasonable care, should have known about the risk of spontaneous migration and perforation.
- 81. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of spontaneous migration and perforation, in light of the likelihood that their product would cause spontaneous migration and perforation, for which Plaintiff suffered.
- 82. Defendants' Mirena® is defective due to inadequate post-marketing warning or instruction.
- 83. Defendants knew, or in the exercise or reasonable care, should have known about the risk that their Mirena® causes spontaneous migration and perforation.
- 84. Defendants failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of spontaneous migration and uterine perforation, in light of the likelihood that the product causes spontaneous migration and perforation, for which Plaintiff suffered.
- 85. Defendants' product does not contain a warning or instruction regarding spontaneous migration and perforation for normal healthy individuals.

- 86. The risk of spontaneous migration and perforation is not an open and obvious risk or a risk that is a matter of common knowledge in regards to Mirena®.
- 87. The Defendants' product was defective in that, when it left the control of Defendant, the product did not conform to representations made by Defendant.
- 88. Defendants falsely represented to Plaintiff that Mirena® was a safe and effective contraceptive option. The representations by Defendants were in fact false, misleading, and inaccurate, as Mirena® is not safe and is dangerous to the health of its users.
- 89. Defendants describe and represent that their product has characteristics that simply do not conform to reality. Rather than acknowledging that Defendants' product causes spontaneous migration and perforation, Defendants describe Mirena® as being safe.
- 90. These representations are in stark contrast to the spontaneous migration and perforation that Mirena® does actually cause.
- 91. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and her health care providers, information about the propensity of Mirena® to cause great harm. Defendants' claims regarding the safety and efficacy of Mirena® failed to provide an accurate and/or adequate warning of Mirena®'s risks to the Plaintiff and her healthcare providers despite Defendants awareness of these risks.
- 92. While Plaintiffs believe and aver that Defendants acted negligently and recklessly in making the representations, in the event Defendants is not found to have acted negligently or recklessly, Defendant is still liable for the damages and injuries suffered by Plaintiff pursuant to Ohio Revised Code § 2307.77.

- 93. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in that it did not conform, at the time it left the control of Defendant, to representations made by Defendant.
- 94. As a direct and proximate result of Defendants' violations of the Ohio Products Liability Act in their manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective and failing to warn adequately warn the Plaintiff of the true risks associated with Mirena® use, Plaintiff suffered serious and life-threatening side effects including but not limited to, migration of the Mirena causing perforation of her uterus, subsequent surgical removal of the Mirena®, as well as other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses.
- 95. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

<u>COUNT V</u> Fraudulent Misrepresentation

- 96. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.
- 97. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Mirena®, owed a duty not to deceive the

Plaintiff Rebecca Wojtowicz, her health care providers and the public regarding the character, safety, quality and/or effectiveness of their product.

- 98. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio Revised Code § 2307.71 *et seq.*
- 99. Since the drug's approval in 2000, and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and/or effectiveness, including, but not limited to, the Simple Style program.
- 100. At the time of Defendants' fraudulent misrepresentations, Plaintiff Rebecca Wojtowicz was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.
- 101. Defendants breached their duties to Plaintiff Rebecca Wojtowicz by providing false, incomplete, and misleading information regarding Mirena®.
- 102. Defendants acted with deliberate intent to deceive and mislead Plaintiff Rebecca Wojtowicz, her medical providers, and the public.
- 103. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.
- 104. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered serious and life-threatening side effects including but not limited to, migration of the Mirena resulting in uterine perforation, subsequent surgical removal of the Mirena®, as well as other severe and personal injuries, physical pain and mental

anguish, diminished enjoyment of life, medical, health, and incidental and related expenses.

105. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff Rebecca Wojtowicz, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT VI Loss of Consortium

- 106. Plaintiff incorporates by reference each proceeding and succeeding paragraph as though set forth fully at length herein.
- 107. As a result of the foregoing acts and omissions, and the resulting injuries, including but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff Rebecca Wojtowicz, Plaintiff Eric Wojtowicz has suffered the loss of companionship, society, services, and consortium of his wife.

COUNT VII Punitive Damages (R.C. § 2307.80)

- 108. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.
- 109. Plaintiff's injury was the result of misconduct of Defendant that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.

- 110. Defendants fraudulently and in violation of applicable regulations of the FDA withheld from the FDA information known to be material and relevant to the harm that the Plaintiff suffered or misrepresented to the FDA information of that type.
- 111. Defendants engaged in fraudulent and malicious conduct towards the Plaintiff, her medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the public.
- 112. By reason of the foregoing, the Defendant is liable to the Plaintiff for punitive damages, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective under the Ohio Product Liability Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants, jointly and severally, as follows:

- A. For an award of compensatory damages, including damages against Defendants and each of them for pain and suffering, medical and hospital expenses, loss of income, permanent disability, and other damages according to proof at trial in excess of \$75,000;
- B. For an award of punitive or exemplary damages against Defendants and each of them in excess of \$75,000;
- C. For reasonable attorneys' fees and costs;
- D. For pre-judgment interest; and
- E. For such further and other relief the court deems just, equitable, and proper.

Dated: March 28, 2014 Respectfully Submitted,

/s/Pamela A. Borgess

Pamela A. Borgess (0072789) James G. O'Brien (0088460) ZOLL, KRANZ & BORGESS, LLC 6620 W. Central Ave., Suite 100 Toledo, OH 43617

Tel. (419) 841-9623 Fax: (419) 841-9719

Email: pamela@toledolaw.com
Email: jim@toledolaw.com

Counsel for Plaintiffs

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

/s/Pamela A. Borgess

Pamela A. Borgess (0072789)